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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,727	VAGHEFI ET AL.	
	Examiner	Art Unit	
	LESLIE A. ROYDS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7,9 and 11-25* is/are pending in the application.

4a) Of the above claim(s) *12-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-5,7,9,11,24-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 4-5, 7, 9 and 11-25 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment and submission filed August 13, 2009 has been received and entered into the present application. Accordingly, prosecution has been reopened.

Claims 1, 4-5, 7, 9 and 11-25 remain pending. Claims 12-23 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 1, 4-5, 7, 9, 11 and 24-25 remain under examination. Claim 26 is cancelled. Claims 1 and 25 are amended.

Applicant's arguments, filed August 13, 2009, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter (New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5, 7, 9, 11 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In particular, the specification and claims as originally filed fail to provide adequate written description for the newly added limitation directed to wherein the water insoluble matrix material is elastic (claim 1).

Applicant directs the Examiner to para.[0058] in support of this limitation, which states: "In another embodiment, the opiate component is chemically bonded to the matrix…Those embodiments in which highly cross-linked polymers are used as the matrix, the tenacity of the composition is due to the hardness of the matrix. In alternative embodiments in which low cross-linked polymers or viscoelastic polymers are used as the matrix, the tenacity of the composition is due to the elasticity of the matrix. In these embodiments, matrix tenacity, or resistance to opiate component release, is imparted to the composition by the use of pharmaceutically acceptable cross-linked polymers such as cholestyramine resin."

Applicant also directs the Examiner to para.[0101] in support of this limitation, which states: "The matrix material appears to be very closely associated with the drug particle surface, wetting the drug particle surface, and is not simply admixed with the particles. Each drug particle can be viewed as being individually encapsulated by matrix material, independent of the presence of any third encapsulating component. The matrix can serve the encapsulating function itself. Also, the grinding appears to only disturb the initial dissolution delay function of the microspheres. It also suggests that the matrix material retains its elastic-like nature through the manufacturing process."

However, the disclosure of the elasticity of the matrix when low cross-linked polymers or viscoelastic polymers are used or the disclosure of the "elastic-like" nature of the matrix in the exemplary compositions of Examples 1-6 that contain specific combinations of components to be crushed and tested for dissolution properties of the water-soluble active ingredient fails to provide adequate written support

to now broaden the claims to read on an "elastic matrix" when *any* matrix material is used. This is a concept that is not adequately supported by the written description of the invention as provided in the specification and claims as originally filed because the disclosure of an "elastic" matrix when *specific* matrix materials are used (such as, e.g., the low cross-linked polymers or viscoelastic polymers as disclosed in para.[0058] or the specific matrices used in the exemplary compositions identified as 1-6 in the instant specification) does not provide adequate support to then broaden the claims to read upon this same property of matrix "elasticity" using *any* material as the matrix. This newly amended limitation represents a narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure and clearly circumscribes a concept that was not in Applicant's possession at the time of the invention. Note also, for the record, that the disclosure of the matrix being "elastic-like" as recited in para.[0101] of the instant specification fails to provide adequate description of the matrix being "elastic" *per se* as is now instantly claimed. This is because the "elastic-like" property of the matrix is clearly indicative of the fact that it has similar properties of "elasticity" but is not, *per se*, "elastic".

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms of *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of wherein the water insoluble matrix material is elastic (claim 1).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5, 7, 9, 11 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth at p.2-8 of the previous Office Action dated April 14, 2009, of which said reasons are herein incorporated by reference.

Applicant's amendments to instant claim 25 and cancellation of instant claim 26 has rendered the instant rejection moot over the previously pending limitations directed to "wherein a pressure-pulse is applied to a flowable mixture of said coating material and said active water soluble compound to form a pressure-treated matrix" (previous claim 25) or "wherein said pressure-treated matrix is spray cooled to form microspheres" (previous claim 26).

Response to Applicant's Arguments

Applicant states that, regarding the previous limitation of "prior to coming in contact with water", the instant claim has been amended to replace the limitation of "water" with "aqueous environment." Applicant references the disclosure provided in the instant specification at para.[0014] and [0019] and Example 7 to provide adequate support for this amended limitation. Applicant further states that, regarding the previous limitation of "does not substantially modify the dissolution rate of said active water soluble compound thereafter", the skilled artisan would clearly recognize that the only ingredient

that is of dissolution interest is the active water soluble compound and again directs the Examiner to Example 7 is support of this position.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant argues that the specification provided adequate written support for the limitation directed to crushing, compressing, fracturing, tumbling, rolling or milling said matrix before coming into contact with an aqueous environment. This is unpersuasive. Applicant's instant specification fails to clearly, precisely or deliberately define the application of mechanical stress *prior to coming into contact with an aqueous environment*. This is at least evident at the previously cited portion of the instant specification reproduced at p.3-4 of the previous Office Action dated April 14, 2009, which fails to specifically teach that the mechanical stress is applied prior to contacting an aqueous environment. It is also evident at para.[0014] and [0019], upon which Applicant relies upon in his Remarks to demonstrate sufficient written basis for this limitation, because each of para.[0014] and [0019] is specifically directed to crushing the composition according to the invention to then be administered to a person via injection or inhalation, i.e., to a human body, which is clearly a much broader concept that simply "contacting an aqueous environment". Moreover, Applicant's reliance upon the disclosure found in Example 7 does not provide additional disclosure to remedy the lack of written description of this limitation because, at most, the stress applied to the compositions in Example 7 is limited only to crushing and there is no indication therein that, specifically, an aqueous environment is, at some point, contacted following such crushing. Accordingly, it is maintained that this limitation of the instant claims fails to find adequate written basis in either the specification or claims as originally filed.

Secondly, and lastly, Applicant argues that the skilled artisan would clearly recognize that the only ingredient that is of dissolution interest is the active water soluble compound. This also remains unpersuasive. The disclosure found in Example 7 is directed to how the dissolution of the water-soluble active ingredient may be determined and is not directed to the actual alleged property of the composition,

i.e., the dissolution rate of the composition *per se*. Accordingly, Applicant is again directed to his disclosure at p.6-7, which very clearly describes this dissolution property of increasing the aqueous dissolution of the active water-soluble compound by less than about 15% of the total pharmaceutically effective dosage amount in the first hour and "the dissolution rates of the preferred compositions are not substantially modified after the first hour of testing." The description of these "preferred compositions" clearly circumscribes the disclosed composition, which contains the active water-soluble compound and the matrix, *not* simply the active water-soluble compound alone. In other words, Applicant has only described this increase in aqueous dissolution of the *composition per se*, not the water-soluble compound alone. Accordingly, it is maintained that this limitation of the instant claims fails to find adequate written basis in either the specification or claims as originally filed.

For these reasons *supra*, and those previously made of record at p.2-8 of the Office Action dated April 14, 2009, rejection of claims 1, 4-5, 7, 9, 11 and 24-25 is proper.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, 7, 9, 11 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Palermo et al. (U.S. Patent No. 6,228,863; 2001), already of record, for the reasons of record set forth at p.8-14 of the previous Office Action dated April 14, 2009, of which said reasons are herein incorporated by reference.

Newly amended claim 1 remains properly included in the instant rejection because:

(1) Palermo et al. teaches a controlled release formulation of a opioid analgesic, such as, *inter alia*, oxycodone, wherein the formulation can be a multiparticulate in the form of, e.g., microspheres (see Palermo et al., col.6, l.40-45), that includes a sustained release carrier, which is incorporated into a matrix and applied as a sustained release coating that may further contain plasticizers that are both water-insoluble and enhance the elasticity of the films used for coating the particles (see col.17, l.52-57) and are present in an amount of about 1-50% by weight of the films used for coating (i.e., understood to meet Applicant's "abuse-reducing amount" as recited in instant claim 1, absent factual evidence to the contrary and absent a specific definition by Applicant as to what constitutes an "abuse-reducing amount"; see col.17, l.34-37). Note also that Palermo et al. clearly teaches a particle size of the active ingredient of, e.g., about 0.1 mm to about 2.5 mm (col.14, l.63-67), which is clearly on the order of a few micrometers and, thus, meets Applicant's instantly claimed limitation directed to "micronized" particles of the active water-soluble compound (i.e., the opioid analgesic). Please see Palermo et al. at the abstract, col.3, l.38-col.5, l.10; col.14, l.33-68 and col.17, l.24-41. Thus, the application of a matrix formed from the sustained release coating containing water-insoluble plasticizers to a particulate formulation of the opioid analgesic to wet the surfaces of the particles thereof to form the final formulation (which, as described above, may be in the form of microspheres) is evidence that the particles of the opioid analgesic would be distributed throughout this water-insoluble matrix via the act of immersing the particles of the opioid compound in the coating.

(2) The limitations directed to the ability of the composition to increase the aqueous dissolution of the active water soluble compound when subjected to crushing, etc. are characterizations of the function and/or effect of the composition when subjected to such mechanical actions. Though Palermo et al. is silent as to such functions of the disclosed composition, it is noted that the teaching of a composition with identical formulation components and characteristics (i.e., same active agents, same matrix, same structural relationships between the components, etc.) must necessarily possess the same functional

properties of increasing the aqueous dissolution of the active water soluble compound when subjected to crushing etc., even though such properties may not have been appreciated by the patentee(s) at the time of the invention. This is because products of identical chemical composition cannot have mutually exclusive properties because a chemical composition and its properties are inseparable. Thus, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims must be necessarily present, absent factual evidence to the contrary. Please see MPEP §2112. Equivalent rationale is applied to newly amended claim 9, which limits the subject matter to the act of "crushing said matrix".

In re Best (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe includes functions and/or properties that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the newly cited function and/or property at the time of invention, so long as the function and/or property can be demonstrated to be reasonably expected to be present. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

Newly amended claim 25 properly included in the instant rejection because the claim clearly defines specific steps of making the instantly claimed abuse-resistant composition of instant claim 1, i.e., product-by-process claims, wherein the surfaces of said particles of active water-soluble compound are wetted with said coating material by applying a pressure-pulse to a dispersion of said active water-soluble compound particles in a water-insoluble fluid matrix of said coating material, thereby forming a flowable

dispersion of said discrete particles in said water-insoluble fluid matrix, and wherein said microspheres are formed by spraying said flowable dispersion of said discrete particles into a chilling zone maintained at a temperature below the solidification temperature of said coating material. Though it is noted that Palermo et al. does not explicitly teach these steps of instant claim 25 to prepare the composition of instant claim 1, Applicant is reminded that these limitations are process limitations (i.e., directed to a process of obtaining the final abuse-resistant composition) and, thus, fails to materially or structurally limit the claimed composition or components thereof as a whole since the prior art already teaches the instantly claimed product. Accordingly, since the cited reference(s) clearly anticipates the same composition for the reasons *supra* and those already of record, the process Applicant intends to prepare the claimed composition is immaterial to the composition as a whole. As directed by the MPEP at §2113, "Even though product-by-process claims are limited by and defined by the process, *determination of patentability is based on the product itself.* The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" (see *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985 and MPEP §2113)). Moreover, MPEP §2113 states, "Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, *the burden shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product."* (emphasis added)

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that Palermo et al. fails to disclose or suggest (1) a means for retarding the aqueous extraction of the active opioid if the composition is crushed, milled or otherwise mechanically stressed before ingestion into the body or (2) that discrete micronized particles of

the active compound are surface-wetted with water-insoluble material and dispersed in a matrix of the same material that is elastic and present in an "abuse-reducing" amount. Applicant alleges the Examiner has not identified where the reference teaches such a composition. Applicant further alleges that the best evidence that Palermo et al. do not disclose compositions of the presently claimed invention is to show that OxyContin® tablets do not exhibit the abuse-resistant properties of the instantly claimed invention. Still further, Applicant opines that OxyContin® tablets comprise ingredients identified in Palermo et al. for formulation as sustained release compositions and presents various graphs and tables supporting this allegation that OxyContin® tablets clearly result in rapid release of oxycodone and, therefore, do not meet the physical and chemical properties required by the instant claims.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant alleges that Palermo et al. fails to disclose or suggest a means for retarding the aqueous extraction of the active opioid if the composition is crushed, milled or otherwise mechanically stressed before ingestion into the body. This is, and will remain, unpersuasive. The composition of Palermo et al. meets each and every physical and structural requirement of the instant claims (even as amended; see the reasons and citations provided *supra* as to how these limitations are met) and, therefore, the functional properties thereof (as described by Applicant's claims) must necessarily be present in the composition of Palermo et al., absent factual evidence to the contrary, because products of identical composition cannot have mutually exclusive properties. See MPEP §2112. Thus, whatever properties Applicant may have newly recognized from this same combination and arrangement of elements as taught in the prior art by Palermo et al. is a function of the composition and must also be present in the invention of Palermo et al., if subjected to the same conditions, absent factual evidence to the contrary.

Moreover, note that the invention of Palermo et al. is clearly functional at least to reduce the abuse potential of the opioid analgesic contained therein, though the reference may not explicitly describe the exact mechanism by which it functions to do so. However, even if, *arguendo*, Palermo et al. did

describe a mechanism for reducing abuse potential that differed from Applicant's mechanism (which the Examiner does not necessarily concede), the mechanism by which each composition allegedly functions to inhibit abuse of the opioid contained therein is immaterial to the fact that Palermo et al. very clearly teaches the identical physical and structural components as that instantly claims and, therefore, the properties that Applicant alleges are present in his composition must necessarily be present in the composition of the prior art because, again, products of identical composition cannot have mutually exclusive properties. Again, see MPEP §2112. The discovery or explanation as to how the abuse potential is reduced, such as, e.g., instant claim 1, fails to patentably distinguish the instant claims over that of the prior art to Palermo et al. because the discovery of previously unappreciated properties that appear to be necessarily present in the invention of Palermo et al., which has the same physical and structural properties as the invention instantly claimed, does not amount to a patentably new composition unless Applicant demonstrates that such characteristics are, in fact, *not* present in the prior art product.

Secondly, Applicant alleges that Palermo et al. fails to disclose or suggest that discrete micronized particles of the active compound are surface-wetted with water-insoluble material and dispersed in a matrix of the same material that is elastic and present in an "abuse-reducing" amount and also alleged that the Examiner has not identified where the reference teaches such a composition as that instantly claimed. This is both unpersuasive and an allegation without merit. The rejection very clearly identified the portions of Palermo et al. that teach the elements and structure instantly claimed. Applicant's attention is directed to the citations provided in the original rejection and those provided *supra* regarding how Palermo et al. meets the newly amended limitations of the instant claims, if he is need of clarification.

Fourthly, Applicant attempts to demonstrate that the composition of Palermo et al. does not have the same characteristics as those recited in the instant claims by showing that an OxyContin® tablet, which Applicant alleges is a composition according to Palermo et al., exhibits rapid release of oxycodone

when crushed. This comparison is clearly unpersuasive. Applicant has once again failed to make a comparison of the claimed product to the cited prior art of record to demonstrate that the instantly claimed product, in fact, has different properties from that of the prior art to Palermo et al. Since Palermo et al. discloses compositions that contain the same physical and structural elements to that of Applicant's claims, Applicant would need to provide some evidence or reasoning to support his position that the composition of *Palermo et al., which is the closest prior art of record*, does not also contain these same properties that are allegedly in Applicant's product. The closest prior art product here is not simply an OxyContin® tablet that is commercially available; rather, it is the prior art product of Palermo et al. Therefore, the rapid release of OxyContin® that may be achieved via crushing a commercial OxyContin® tablet clearly ignores both the teachings of Palermo et al. and the fact that Palermo et al. very clearly provides for an abuse-resistant composition that inhibits the release of the opioid so as to avoid this property of rapid release that would be achieved via using an OxyContin® tablet without such an abuse-resistant mechanism. Accordingly, this proffered comparison of Applicant's abuse-resistant product to a non-abuse-resistant composition of an opioid is very clearly unpersuasive because (1) a non-abuse resistant OxyContin® tablet is *not* the closest prior art of record and is also clearly not a product according to the specifications of Palermo et al. (because Palermo et al. teaches an abuse-resistant composition and a commercially available OxyContin® tablet is most certainly *not* abuse-resistant) and (2) such a non-abuse resistant composition would have been expected by the skilled artisan to result in rapid release of the opioid because it contains no compounds to inhibit such release, as are found in the invention of Palermo et al. Accordingly, the rejection is maintained.

For these reasons *supra*, and those previously made of record at p. 8-14 of the Office Action dated April 14, 2009, rejection of claims 1, 4-5, 7, 9, 11 and 24-25 is proper.

Conclusion

Rejection of claims 1, 4-5, 7, 9, 11 and 24-25 is proper.

Claims 12-23 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

August 24, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614